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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,213	11/19/2001	Marc Alizon	3495.0050-16	8195

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WASHINGTON, DC 20005

EXAMINER
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PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/988,213

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 07/003,764.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**Detailed Office Action**

***Status of the Claims***

1. Acknowledgement is hereby made of receipt and entry of the preliminary amendment filed 19 November, 2001, wherein claims 1-43 were canceled without prejudice or disclaimer and new claims 44-46 submitted. Claims 44-46 are currently under examination.

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***35 U.S.C. § 120***

2. Applicants are reminded that if priority under 35 U.S.C. § 120 based upon a previously filed copending application is desired, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. **If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application.** If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicants are advised that U.S. Serial No. 07/810,908 has matured into U.S. Patent No. 6,544,728. The first paragraph of the specification should be amended to reflect this development.

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***35 U.S.C. § 112, Second Paragraph***

3. Claims 44-46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims reference **Figure 6** which does **not** appear in the disclosure. Appropriate correction is required.

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**35 U.S.C. § 112, First Paragraph**

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

5       The specification shall contain a written description of the  
invention, and of the manner and process of making and using it, in  
such full, clear, concise, and exact terms as to enable any person  
skilled in the art to which it pertains, or with which it is most  
nearly connected, to make and use the same and shall set forth the  
best mode contemplated by the inventor of carrying out his  
10       invention.

5. Claims 44-46 are rejected under 35 U.S.C. § 112, first  
paragraph, as containing subject matter which was not described in  
the specification in such a way as to reasonably convey to one  
15       skilled in the relevant art that the inventor(s), at the time the  
application was filed, had possession of the claimed invention. In  
*re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In  
*re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). To  
satisfy the written description requirement, a patent specification  
20       must describe the claimed invention in sufficient detail that one  
skilled in the art can reasonably conclude that the inventor had  
possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v.*  
*Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue  
raised in this application is whether the original application  
25       provides adequate support for the terms **"at least a portion of a  
pol gene"**, **"at least a portion of the nucleic acid sequence of a  
pol gene"**, or **"at least one domain in a pol gene of HIV-1<sub>BRU</sub>"**. An  
applicant shows possession of the claimed invention by describing  
the claimed invention with all of its limitations using such  
30       descriptive means as words, structures, figures, diagrams, and  
formulas that fully set forth the claimed invention. *Lockwood v.*  
*American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961,  
1966 (Fed. Cir. 1997). The claimed invention as a whole may not be  
adequately described where an invention is described solely in  
35       terms of a method of its making coupled with its function and there

is no described or art-recognized correlation or relationship between the structure of the invention and its function.

5 A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

20 An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of 25 identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description 30

requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The disclosure describes the cloning and characterization of a novel human immunodeficiency virus type 2 (HIV-2). The nucleotide sequence, and deduced amino acid sequence, of a full-length *pol* gene was determined from a proviral molecular clone (see Examples 4 and 5, respectively). **A single Gag peptidic fragment is disclosed in Example 6 corresponding to nt 991-1053.** This is the **only gag** fragment disclosed in the application. This particular region was chosen because of its genetic relatedness to HIV-1. However, the disclosure fails to identify any other fragments or portions of the *pol* gene or polypeptide. The disclosure fails to identify other regions within this structural gene that may be useful as diagnostic reagents or for the generation of polypeptide fragments and immunological reagents. The disclosure also fails to identify suitable nucleotide sequences that hybridize to the *pol* gene under the claimed hybridization parameters. Thus, the skilled

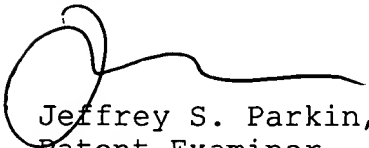
artisan would reasonably conclude that applicants were in possession of the full-length *pol* gene and a single fragment corresponding to nt. 991-1053. However, the skilled artisan would also reasonably conclude that applicants were not in possession of the large genus corresponding to *Pol* polypeptide fragments, nucleic acid sequences encoding said fragments, and nucleic acid probes that are capable of hybridizing to said fragments under the recited conditions. Thus, it appears that applicants are attempting to capture subject matter to which they are clearly not entitled.

#### *Correspondence*

6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

7. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

26 June, 2003